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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

RAHSAN A. HAKIM and
ADONIIAH A. RAHSAN,
d/b/a SUNDIAL HERBAL PRODUCTS,

Defendants.

18 Civ. 5726

COMPLAINT

Plaintiff the United States of America, by its attorney, Geoffrey S. Berman, United States Attorney for the Southern District of New York, alleges for its complaint as follows:

1. Rahsan A. Hakim and Adoniiah A. Rahsan ("Defendants"), doing business as Sundial Herbal Products, sell drugs and dietary supplements that they claim, without justification, will treat syphilis, asthma, diabetes, cancer, AIDS, high blood pressure, and other diseases. These drugs and claims do not comply with the Federal Food, Drug, and Cosmetic Act (the "Act") and its implementing regulations. The U.S. Food and Drug Administration ("FDA") has repeatedly inspected Defendants' business and sent them warning letters seeking appropriate corrective actions. Yet Defendants have repeatedly failed to correct their violations and continue to violate the Act.

2. Defendants' violations pose a threat to public health because their disease treatment claims may cause consumers to delay appropriate medical care for the serious medical issues described above. Further, Defendants cannot guarantee the identity, purity, strength, and composition of their dietary supplements. Injunctive relief is necessary because Defendants have demonstrated that, despite repeated warnings, they will continue to violate the Act.

3. The United States brings this action to enjoin this ongoing public health threat pursuant to 21 U.S.C. §§ 331(a), (d), and (k), and 332(a).

JURISDICTION AND VENUE

4. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

5. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

6. Defendants Rahsan A. Hakim ("Hakim") and Adoniiah A. Rahsan ("Rahsan") are individuals who do business as Sundial Herbal Products ("Sundial"), an unincorporated entity that Defendants have identified as a partnership.

7. Defendants Hakim and Rahsan have also done business under several other names including Sundial Herbs & Herbal Products, Inc.; Health at Sunrise Inc.; Koromantee Natural & Traditional Health Foods; and Sundial Honey and Herbs Company.

8. Defendant Hakim is Sundial's co-owner and partner. He shares responsibility for overseeing Sundial with his son, Defendant Rahsan. Defendant Hakim has formulated proprietary blends for the tonics that Sundial manufactures. He also gives medical advice through www.sundialherbs.com, where he calls himself a "Bush Doctor" who provides "complete health consultation for what might be ailing you." Defendant Hakim is responsible for Sundial's manufacturing operations and major financial decisions, and has the authority and

duty to prevent, detect, and correct objectionable conditions. Defendant Hakim works at 3609 Boston Road, Bronx, New York.

9. Defendant Rahsan is Sundial's co-owner and partner. He oversees Sundial with his father, Defendant Hakim, and is responsible for quality control and sales. Defendant Rahsan accompanied FDA's investigator during the latest inspection of the facility, answered questions about the company's operations, and identified and provided copies of requested records. Defendant Rahsan has the authority and duty to prevent, detect, and correct objectionable conditions. He also works at 3609 Boston Road, Bronx, New York.

10. In addition, Defendants are affiliated with two other entities that maintain active registrations in New York: Sundial Herbs & Herbal Products Enterprises, Inc., a corporation, and Sundial Herbs & Herbal Products, LLC, a limited liability company. Defendants also own Sundial Herb and Herbal Products, Inc. Ltd., located in Kingston, Jamaica, from which they import components for their drug and dietary supplement products.

DEFENDANTS' OPERATIONS

11. Sundial manufactures, packages, labels, and distributes numerous tonics, herbs, and herbal teas at and from its manufacturing facility, located at 3609 Boston Road, Bronx, New York ("the facility"). Sundial also has an address at 538 Jerusalem Ave., Uniondale, New York.

12. Sundial shares the Boston Road building with the Koromantee Health Food Store ("Koromantee"), which is co-owned by Defendants Hakim and Rahsan and which sells Sundial products to other retail stores and online buyers.

13. Sundial operates the website www.sundialherbs.com through which customers can buy its products. Many of Sundial's products bear the text "www.sundialherbs.com" on

their individual packaging. Sundial also operates a Facebook page, https://www.facebook.com/sundialherbalproducts, which advertises its products.

DEFENDANTS DISTRIBUTE UNAPPROVED NEW DRUGS

14. It is a violation of the Act to introduce or deliver for introduction, or cause to be introduced or delivered for introduction, into interstate commerce a "new drug" that is neither approved by the FDA nor exempt from approval. 21 U.S.C. § 331(d). Specifically, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless the FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j).

Some of Defendants' Products Are Drugs

15. A product is a drug if, among other things, it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease[.]" 21 U.S.C. § 321(g)(1)(B). The intended use of a product may be determined from any relevant source, including labeling. *See* 21 C.F.R. § 201.128.

16. The Act defines "label" as, among other things, "a display of written, printed, or graphic matter upon the immediate container of any article[,]" 21 U.S.C. § 321(k), and "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article," 21 U.S.C. § 321(m). A "label" is directly placed on the product itself, while "labeling" includes descriptions on websites, flyers, and similar accompanying materials.

17. Defendants' products are intended for use to cure, mitigate, treat, and/or prevent numerous diseases or conditions, including but not limited to syphilis, diabetes, poisoning, Ebola, high blood pressure, heart disease, and cancer. Defendants have stated such intended uses

on their product labels and/or labeling, including their website, www.sundialherbs.com, and on the brochures and flyers posted on the website. The intended uses described on Defendants' labels and/or labeling include, but are not limited to, the following:[1]

a. Arthritis Blend: "used . . . for various common ailments like Asthma, Blood Pressure, Diabetes, Liver, Heart, Arthritis and much more"

b. Ashanti Weight Loss Energy Lifter and Appetite Suppresser: "rid the body of inflammations"

c. Asthma Blend: "used . . . for various common ailments like Asthma, Blood Pressure, Diabetes, Liver, Heart, Arthritis and much more"

d. Blood Pressure Blend: "used . . . for various common ailments like Asthma, Blood Pressure, Diabetes, Liver, Heart, Arthritis and much more"

e. Cassava Meal: "cleans the stomach, intestine, and colonic area . . . thereby controlling blood cholesterol levels, prevent[ing] heart disease and constipation and retard[ing] the growth of cancer in the stomach and intestines"

f. Chaney Root: used for rheumatism, syphilis

g. Diabetic Blend: "used . . . for various common ailments like Asthma, Blood Pressure, Diabetes, Liver, Heart, Arthritis and much more"

h. Flax Seed Meal Cereal: "regulates cholesterol and suppresses the growth of cancer cells," "clears the lungs and chest of mucus and [i]nflammation," and "clears bladder, kidney, urinary tract and prostate"

i. Flu and Allergies Blend: "used . . . for various common ailments like Asthma, Blood Pressure, Diabetes, Liver, Heart, Arthritis and much more"

j. Heart Blend: "used . . . for various common ailments like Asthma, Blood Pressure, Diabetes, Liver, Heart, Arthritis and much more"

k. Traditional African Manback Tonic: "used for all weaknesses in male reproductive system, spine, nerves and as a treatment for impotence"

l. Wood and Root Tonic: "[p]rotect from . . . epidemics"

[1] The following descriptions list the product and/or "ingredient" as described by Sundial, followed by the claimed uses as described on their label/labeling.

m. Worms Blend: "used . . . for various common ailments like Asthma, Blood Pressure, Diabetes, Liver, Heart, Arthritis and much more"

18. The intended uses set forth in the labels and/or labeling for the products discussed in Paragraph 17, as well as for many other of Defendants' products, render those products drugs within the meaning of the Act.

Defendants' Drugs Are Unapproved New Drugs

19. A "new drug" is defined as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ; or [a]ny drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." 21 U.S.C. § 321(p).

20. Defendants' drugs are "new drugs" as defined in 21 U.S.C. § 321(p) because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling, nor are they the subjects of safety investigations resulting in such recognition nor have they been used for a material extent or time under such conditions.

21. None of Defendants' drugs is the subject of an FDA-approved NDA or ANDA, or an effective IND.

22. Defendants' drugs are unapproved new drugs, and Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of unapproved new drugs.

DEFENDANTS DISTRIBUTE MISBRANDED DRUGS

23. The introduction or delivery for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

24. Many of Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1), because their labeling fails to bear "adequate directions for use" and the drugs do not fall within a regulatory exemption from that requirement. *See, e.g.*, 21 C.F.R. § 201.115.

25. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce, of misbranded drugs, and 21 U.S.C. § 331(k) by causing their drugs to become misbranded while such articles are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS DISTRIBUTE ADULTERATED DIETARY SUPPLEMENTS

Some of Defendants' Products Are Dietary Supplements

26. The Act defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)[.]" 21 U.S.C. § 321(ff)(1). A dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." 21 U.S.C. § 321(ff)(2). With exceptions not relevant here, dietary supplements are deemed to be food under the Act. 21 U.S.C. § 321(ff)(3).

27. A product that is a dietary supplement may also be a drug if it meets the definition of a "drug" under 21 U.S.C. § 321(g). 21 U.S.C. § 321(ff).

28. Many of Defendants' products are dietary supplements, including but not limited to: Ashanti Weight Loss Energy Lifter and Appetite Suppresser; Asthma; Blood Pressure; Brain Tonic; Diabetics; Flax Seed Oil & Honey Blend; Flu-Allergies Hayfever; Ghanaian Woman Back Tonic; Heart, Hepatitis/Liver; Koromantee; Nerve Tonic; Traditional African Manback Tonic; Traditional All Purpose Seasoning & Digestive Aid; Wood and Root Tonic; and Worms & Parasites. Even though Defendants have not included statements on the products' labels explicitly identifying them as dietary supplements, the products (i) are intended to be ingested, (ii) are intended to supplement (add further nutritional value to) the diet, as opposed to being a conventional food item, by including statements of intended uses beyond taste, aroma, or nutritive value; and (iii) have labels that list at least one ingredient that is a "dietary ingredient" as specified by 21 U.S.C. § 321(ff)(1).

29. In addition to being dietary supplements, Defendants' Ashanti Weight Loss Energy Lifter and Appetite Suppresser, Asthma, Blood Pressure, Diabetics, Ethiopian Flax Seed Oil & Honey Blend, Flu-Allergies Hayfever, Heart, Hepatitis/Liver, Koromantee, Traditional African Manback Tonic, Wood and Root Tonic, and Worms & Parasites are, as discussed in Paragraphs 17 and 18, also drugs within the meaning of the Act.

Defendants' Dietary Supplements Are Adulterated

30. The Act requires dietary supplement manufacturers to operate in compliance with current good manufacturing practice ("cGMP") regulations for dietary supplements. 21 U.S.C. § 342(g)(1). The dietary supplement cGMP regulations are set forth at 21 C.F.R. Part 111. To comply with dietary supplement cGMP regulations, manufacturers must incorporate a set of controls in the design and production stages of the manufacturing process to ensure a finished product of acceptable, predictable, and reliable quality. Dietary supplements not manufactured, prepared, packed, or held in conformance with the cGMP regulations are deemed to be adulterated. 21 U.S.C. § 342(g)(1).

31. FDA most recently inspected Defendants' facility between February 7 and 17, 2017 ("February 2017 inspection"). The February 2017 inspection established that the dietary supplements that Defendants manufacture, prepare, pack, repack, label, hold, and distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not comply with dietary supplement cGMP regulations.

32. During the February 2017 inspection, FDA's investigator documented numerous significant deviations from the dietary supplement cGMP regulations, including, but not limited to, the following:

a. Failure to establish identity specifications for each component used to manufacture finished dietary supplements, as required by 21 C.F.R. § 111.70(b)(1);

b. Failure to establish product specifications for the identity, purity, strength, and composition of Defendants' finished dietary supplements, as required by 21 C.F.R. § 111.70(e);

c. Failure to establish and follow written procedures for the responsibilities of the quality control operations, as required by 21 C.F.R. § 111.103;

d. Failure to follow master manufacturing records to ensure uniformity in the finished batch from batch to batch, as required by 21 C.F.R. § 111.205;

f. Failure to include all required elements of the master manufacturing records, as required by 21 C.F.R. § 111.210;

g. Failure to establish complete batch production records, as required by 21 C.F.R. §§ 111.255(b) and 111.260;

h. Failure to identify each unique lot within each unique shipment of components received to allow Defendants to trace the lot to the supplier and the date received, as required by 21 C.F.R. § 111.155(d)(1);

i. Failure to use equipment that is of appropriate construction to enable it to be suitable for its intended use and to be adequately cleaned and properly maintained, as required by 21 C.F.R. § 111.27(a); and

j. Failure to establish and follow written procedures to fulfill the requirements for returned products, as required by 21 C.F.R. §§ 111.503 and 111.530.

33. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of

food (dietary supplements) that are adulterated within the meaning of the Act, and 21 U.S.C. § 331(k) by causing dietary supplements to become adulterated within the meaning of the Act while such food (dietary supplements) is held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS DISTRIBUTE MISBRANDED DIETARY SUPPLEMENTS

34. Certain of Defendants' products are misbranded food (dietary supplements) within the meaning of:

a. 21 U.S.C. § 343(e)(1), because their labels fail to list the place of business of the manufacturer, packer, or distributor in accordance with 21 C.F.R. § 101. Specifically, the labels of Defendants' Ashanti Weight Loss Energy Lifter and Appetite Suppresser, Koromantee, and Traditional African Manback Tonic fail to include the city, state, and zip code of the manufacturer, packer, or distributor;

b. 21 U.S.C. § 343(i)(2), because Defendants' Wood and Root Tonic contains dietary ingredients (e.g., Nasberry Leaf, Breadnut Leaf, Mahogany Root, Nerve Wiss, Mahogany Bark, and Birch Gum Bark) that are not declared on the product labels, as required by 21 C.F.R. §§ 101.4(a)(1) and 101.36(b)(3);

c. 21 U.S.C. § 343(q)(5)(F), because the labels of Defendants' Ashanti Weight Loss Energy Lifter and Appetite Suppresser, Asthma, Blood Pressure, Diabetics, Flu-Allergies Hayfever, Ghanaian Woman Back Tonic, Heart, Hepatitis/Liver, Koromantee, Nerve Tonic, Traditional African Manback Tonic, Wood and Root Tonic, and Worms & Parasites fail to bear the "Supplement Facts" panel and the amounts of the dietary ingredients therein, as required by 21 C.F.R. § 101.36;

d. 21 U.S.C. § 343(s)(2)(B), because the labels of Defendants' Ashanti Weight Loss Energy Lifter and Appetite Suppresser, Asthma, Blood Pressure, Diabetics, Flu-

Allergies Hayfever, Ghanaian Woman Back Tonic, Heart, Hepatitis/Liver, Koromantee, Nerve Tonic, Traditional African Manback Tonic, Wood and Root Tonic, and Worms & Parasites fail to identify the products using the term "dietary supplement," as required by 21 C.F.R. § 101.3(g); and

e. 21 U.S.C. § 343(r)(6)(C), because the labels and/or website labeling for Defendants' Ashanti Weight Loss Energy Lifter and Appetite Suppresser, Ghanaian Woman Back Tonic, Koromantee, Traditional African Manback Tonic, and Wood and Root Tonic contain specific types of claims that are required to be accompanied by a disclaimer statement in accordance with 21 C.F.R. § 101.93(c) but do not include such disclaimers.

35. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of food (dietary supplements) that are misbranded within the meaning of the Act, and 21 U.S.C. § 331(k) by causing food (dietary supplements) to become misbranded within the meaning of the Act while such food (dietary supplements) is held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS ENGAGE IN INTERSTATE COMMERCE

36. Defendants ship their finished drugs and dietary supplements in interstate commerce, as that term is defined in 21 U.S.C. § 321(b)(1). According to Defendant Rahsan, approximately thirty percent of Defendants' sales are to out-of-state customers. In one instance, inspectors have documented Defendants' sale of drugs and dietary supplements from New York to an address in North Carolina. Such interstate shipments constitute the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of 21 U.S.C. § 331(d), and misbranded drugs and adulterated and misbranded dietary supplements in violation of 21 U.S.C. § 331(a).

37. Defendants also receive components that they use in the manufacturing of their finished drugs and dietary supplements from outside of New York State, including from Jamaica. As such, Defendants' drugs and dietary supplements are manufactured using components that are shipped in interstate commerce. 21 U.S.C. § 331(k).

VIOLATION HISTORY

38. Defendants are aware that their practices violate the Act. FDA has repeatedly warned Defendants about their violations and that continued violations could lead to regulatory action.

39. At the close of the February 2017 inspection, the FDA investigator issued Defendant Rahsan a List of Inspectional Observations ("Form FDA-483") and discussed the observed deviations with him. The FDA investigator informed him that he had 15 days to respond to the Form FDA-483 in writing. Despite Defendant Rahsan's promise to do so, FDA has not received any such response.

40. At the close of an earlier FDA inspection of the facility between January 7 and February 12, 2014, the FDA investigator issued a Form FDA-483 to Defendant Rahsan and discussed the observed deviations with him. Although Defendants responded by letter dated April 17, 2014, with promised corrective actions, such actions were not properly implemented because FDA documented the same or similar violations during the February 2017 inspection.

41. Following yet another inspection of the facility between October 4 and November 15, 2012 ("2012 inspection"), FDA issued a Warning Letter dated May 24, 2013 ("2013 Warning Letter") to Sundial Herbal Products, with Defendant Hakim (under the name "Adoni-iah Hakim") as its owner. The 2013 Warning Letter informed Sundial that its products, Koromantee, Woman Back Tonic, Wood and Root Tonic, Arthritis, Asthma, Diabetics, Flu-Allergy Hayfever, Hepatitis/Liver, and Worms & Parasite were unapproved new drugs, and that

its Woman Back Tonic, Koromantee, Wood and Root Tonic, Arthritis, Asthma, Diabetics, Flu-Allergy Hayfever, Hepatitis/Liver, and Worms & Parasite products were misbranded drugs. The 2013 Warning Letter also detailed Defendants' violations of the dietary supplement cGMP regulations and FDA's food labeling requirements, many of which were the same as, or similar to, those observed during the February 2017 inspection. The 2013 Warning Letter cautioned that failure to promptly correct the violations could lead to legal action without further notice, including an injunction. Although Defendants verbally promised to take all necessary corrective actions at the close of the 2012 inspection, they did not respond in writing to the 2013 Warning Letter.

42. Thus, despite repeated notifications, Defendants remain unable or unwilling to comply with the Act. Unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

CLAIM FOR RELIEF
PERMANENT INJUNCTION PURSUANT TO 21 U.S.C. § 332

43. The allegations set out in Paragraphs 1 through 42 are incorporated by reference as through set forth fully in this paragraph.

44. Defendants have repeatedly violated 21 U.S.C. §§ 331(a), (d), and (k).

45. The Court should enjoin Defendants' conduct pursuant to 21 U.S.C. § 332(a) and the inherent equitable authority of this Court.

46. Unless enjoined by an order of the Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (d), and (k).

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors,

assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done, any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any unapproved new drug;

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any drug that is misbranded under 21 U.S.C. § 352(f)(1), any food (dietary supplement), within the meaning of 21 U.S.C. § 321(ff)), that is adulterated under 21 U.S.C. § 342(g)(1) or misbranded under 21 U.S.C. § 343(e)(1), (i)(2), (q)(5)(F), (s)(2)(B), and/or (r)(6)(C).

C. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of its components in interstate commerce to become misbranded under 21 U.S.C. § 352(f)(1), and by causing food (dietary supplements), within the meaning of 21 U.S.C. § 321(ff), that Defendants hold for sale after shipment of one or more of its components in interstate commerce to become adulterated under 21 U.S.C. § 342(g)(1) or misbranded under 21 U.S.C. § 343(e)(1), (i)(2), (q)(5)(F), (s)(2)(B), or (r)(6)(C).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from introducing or delivering for introduction, or causing the introduction or delivery for introduction into interstate commerce, of any drug unless and until:

A. An approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drug; or

B. Defendants have removed from (1) product labels; (2) labeling; (3) promotional materials; (4) websites owned, controlled by, or related to Defendants, including but not limited to www.sundialherbs.com, and any future website(s) created, controlled by, or related to Defendants; and (5) any other media over which Defendants have control, all representations about the intended use(s) of Defendants' products that cause such products to be drugs as defined by the Act. For all products for which Defendants have removed claims that caused such products to be drugs within the meaning of the Act, and such products meet the definition of a food (dietary supplement), Defendants shall comply with the dietary supplement provisions of the Act and its implementing regulations before introducing such products into interstate commerce as dietary supplements.

III. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from manufacturing, preparing, processing, packing, labeling, holding, and distributing food (dietary supplements) at or from the facility, or at or from any other location(s) at which Defendants manufacture, prepare, process, pack, label, hold, and/or distribute food (dietary supplements), now or in the future, unless and until Defendants bring their manufacturing, preparing, processing, packing, labeling, holding, and distributing operations into compliance with the Act and dietary supplement cGMP, and unless and until Defendants have revised their labels and

labeling and otherwise ensure that all their labels and labeling comply with the Act and applicable regulations;

IV. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any drug and/or food (dietary supplement) as often as necessary to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished;

V. Order that Plaintiff be granted judgment for its costs herein; and

VI. Grant such other and further relief as it deems just and proper.

Dated: New York, New York
June 25, 2018

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